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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/252,710 06/02/94 RIVIERE I 8141113

HM22/0719

EXAMINER

FREDMAN, J

ART UNIT	PAPER NUMBER
1655	33

DATE MAILED: 07/19/99

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No. <b>08/252,710</b>	Applicant(s) <b>Riviere et al</b>
Examiner <b>Arun Chakrabarti</b>	Group Art Unit <b>1655</b>



Responsive to communication(s) filed on Jun 14, 1999

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

Claim(s) 1-4, 6-31, and 35-44 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) 38-41 is/are allowed.

Claim(s) 1-4, 6-31, 35-37, and 42-44 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 30

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Specification***

1. The objection is withdrawn in view of the amendment.

### ***Claim Rejections - 35 USC § 112***

2. Claims 1-4, 6-31, 35-37 and 42-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP 608.04(a) states “Matter not in the original specification, claims, or drawings is usually new matter. Depending on circumstances such as the adequacy of the original disclosure, the addition of inherent characteristics such as chemical or physical properties, a new structural formula or a new use may be new matter. See Ex parte Vander Wal, et al. , 1956 C.D. 11; 705 O.G. 5 (physical properties), Ex parte Fox , 1960 C.D. 28; 761 O.G. 906 (new formula) and Ex parte Ayers, et al. , 108 USPQ 444 (new use).”

Here, the new limitation to a “consensus splice site” as found in claims 1, 10 and 21, lacks basis in the original specification. The applicant cites the use of a splice site from the MOV-9 vector on page 29 of the specification in support of this broad term, but since many different consensus splice sites may exist, built around the basic GT-AG site, this term represents a broad term which is not supported by the narrower disclosure of the specification. In the absence of any specific support, this term represents new matter. Besides deletion of the term, which would

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moot the new matter rejection, two other possible courses of action may address this rejection.

Amendment to limit the claims to the MOV-9 consensus splice site would appear acceptable, since this site is fully taught in the specification. Alternately, declarations or other evidence supporting a broader interpretation of the specification might be used to overcome this rejection.

***Claim Rejections - 35 USC § 103***

3. The rejection of claims 35-37 under 35 U.S.C. § 103 is withdrawn in view of the amendment.

***Allowable Subject Matter***

4. Claims 38-41 are allowed.

***Response to Arguments***

5. Applicant's arguments filed June 14, 1999 have been fully considered but they are not persuasive.

Applicant argues that the term "splice acceptor site" is a sequence which conforms with the consensus splice acceptor site. Applicant further argues that the MOV-9 splice acceptor site, a natural site found in MMLV, is a consensus splice acceptor site as understood by the Mount and Shinnick references. Applicant lastly argues that this was well known in the art.

These arguments are not found persuasive for a variety of reasons. Initially, the term "consensus sequence" must be defined as it relates to this issue. In Walker et al, *The Language of Biotechnology, A Dictionary of Terms*, "consensus sequence" is defined as "The sequence that gives the most common nucleotide at each position in cases where there are a number of minor

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variations between nucleotide sequences that have the same function (e.g., promoters).” Thus, the question of whether the specification describes a “consensus sequence” depends upon two factual inquiries, i) whether MOV-9 is, in fact, inherently a “consensus sequence” and ii) whether this inherent property can properly serve as support for the broader term. A related issue is whether this inherency would also then serve to support a prior art rejection, but this will be deferred as the new matter rejection will be maintained.

Applicant provides no citations to the specification to provide support for the term “consensus sequence” in the claims. Applicant identifies no evidence of record in the specification indicating that the MOV-9 site was envisioned as a consensus sequence. Applicant cites Mount to indicate that splice sequences can be aligned to form consensus sequences. Applicant finds no proof in Mount that MOV-9 is, however, consensus sequence. Applicant cites Shinnick, who states that the MMLV genome has a 3' splice acceptor with a 6/7 match to a consensus sequence. If this sequence is identical to MOV-9, then Applicant's argument that this would provide support that it was well known in the art that MOV-9 is a consensus sequence is factually inconsistent with the evidence. In fact, this evidence teaches away from MOV-9 being a consensus sequence, since the sequence only matches 6/7 with the consensus sequence. If this sequence is not MOV-9, it is not relevant to the teachings in the specification. As a final point, MPEP 716.01(c) states “The arguments of counsel cannot take the place of evidence in the record. In re Schulze , 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Here, no evidence, such as nucleic acid alignments, is presented to demonstrate that MOV-9 is a consensus

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sequence, simply argument. For these reasons, the factual evidence of record, mostly Shinnick, argue that MOV-9 is not, inherently, a consensus sequence.

While the above conclusion, based upon the evidence presented, is sufficient to retain the new matter rejection, the second question above will be addressed. MPEP 2163.05 notes “The court acknowledged that while a claim may be broader than the specific embodiment disclosed in the specification, the “claims may be no broader than the supporting disclosure.” Thus, a narrow disclosure will limit claim breadth.” Here, the supporting disclosure gives no broader teaching regarding consensus splice sites. Further, it is likely that, based upon the sequences chosen, multiple different consensus splice sites could be created. In fact, Mount, on page 459, expressly discloses multiple different consensus splice sites. Thus, even if, for argument’s sake, the conclusion above was not found persuasive and the single sequence of MOV-9 was found to inherently represent a consensus sequence, the recitation of the single sequence would still not support the broader term because the specification would not have provided descriptive support for the breadth of the term. This narrow disclosure, as noted above, limits claim breadth. Therefore, the new matter rejection will be maintained both on the grounds that MOV-9 is not a consensus sequence, and that MOV-9 does not provide support for the broader term of “consensus sequence”.

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***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeff Fredman, Ph.D. whose telephone number is (703) 308-6568.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).



**Jeffrey Fredman**  
**Primary Patent Examiner**  
**Art Unit 1655**

July 15, 1999